

UCFE Program Coverage Ruling No. 97-1

Human Subjects for Research Studies
Conducted by
U.S. Department of Agriculture,
Agricultural Research Service

Ruling: Human subjects who participate in nutritional research studies conducted by U.S. Department of Agriculture (USDA), Agricultural Research Service (ARS), do not perform "Federal Service" within the meaning of 5 U.S.C. 8501(1).

Statement of Facts: In holding that human subjects participating in ARS nutritional studies do not perform "Federal service," I have considered the following factors:

1. Title XIV of the Food and Agriculture Act of 1977 (Public Law 95-113) provides that USDA is the lead Federal agency for agricultural research in the field of human nutrition and on the nutritive value of foods. Since 1953, the ARS is the USDA agency in charge of conducting nutritional studies.

2. Individuals who participate as "human subjects" in these nutritional studies are covered by the Common Rule for the Protection of Human Subjects (45 CFR Part 46, 7 CFR Part 1c, and ARS Directive 605.1).

3. Human subjects do not earn annual leave, sick leave, nor are they covered under any Federal employee retirement system.

4. On August 2, 1990, the Internal Revenue Service (IRS) ruled in a non-precedential decision that human test subjects in medical tests conducted by the Food and Drug Administration are not employees and do not receive "wages" for income tax withholding or Federal employment tax purposes. Priv. Ltr. Rul. 91-06-004 (Aug. 2, 1990).

5. On January 24, 1994, in a Federal Employment Tax Determination letter mailed to the Bionetics Corporation, the IRS ruled that an individual's participation as a human test subject in USDA-sponsored research was as an independent contractor and not an employee of the firm conducting the research. This letter was obtained from the ARS on August 16, 1996.

Discussion/Analysis: The purpose of the ARS nutritional research is to carry out the policy of the United States as stated in Section 1421(b) of the Food and Agricultural Act of 1977: "It is hereby declared to be the policy of the United States that the Department of Agriculture conduct research in the fields of human nutrition and on nutritive value of foods and conduct human nutrition education activities...."

The individuals who agree to be human subjects for this research are treated according to the principles contained in the Common Rule for the Protection of Human Subjects, and in accord with the Nuremburg Code, the Declaration of Helsinki, and the Public Health Service Guidelines. These guiding principles are designed to ensure that human subjects are fully informed of the purpose and planned procedures to be utilized in the research, and that the individual's decision to participate is voluntary without coercion or undue influence. The human subjects receive a \$35 per day stipend for as long as they participate in the study. The ARS considers the \$35 per day stipend to be too small to influence or coerce an individual's decision to volunteer to be a human subject in its nutritional research studies.

The human subjects participating in these ARS nutritional studies enter into a consent agreement with the ARS. The consent agreement stipulates that the human subjects participating in the study must observe the regimen prescribed by the ARS. The human subjects agree to provide blood and other bodily samples for analyses by the research study staff. The human subjects may elect to end their participation in the study at any time prior to its completion, and failure of the human subject to comply with the experimental protocol and/or established rules will result in the human subject being asked by the ARS to leave the study.

Prior to October 1995, the ARS utilized contractors (e.g., the Bionetics Corporation) for assistance in conducting the metabolic research studies including the payment of the human subjects' stipends. In 1995, the California Employment Development Department (CEDD) informed the contractor at the ARS' Western Human Nutrition Research Center (WHNRC) that human subjects participating in nutritional studies at the WHNRC were employees of the contractor. Under California State law, the contractor became liable for State unemployment taxes based on the payment of the \$35 per day stipend. In October 1995, the WHNRC assumed the responsibility for the payment of the human subjects' stipends, and the issue arose whether these subjects perform "Federal Service." All stipends provided to human subjects are now paid by the ARS.

The Unemployment Compensation for Federal Employees (UCFE) program provides unemployment compensation coverage for Federal civilian employees. In order to be eligible to receive unemployment compensation under the UCFE program, an individual must perform "Federal Service" as defined at 5 U.S.C. 8501(1). The term "Federal Service," in part, is defined to be "service performed after 1952 in the employ of the United States or an instrumentality of the United States which is wholly or partially owned by the United States...." (Emphasis added.) Therefore, for UCFE program coverage purposes, an individual must be a civilian employee of the United States Federal Government and not an independent contractor.

In reviewing this matter I have examined the relevant statutes, regulations, and consent agreements in addition to the decisions and determinations of the CEED and the IRS in determining whether human subjects participating in nutritional research with the ARS perform service as employees or are independent contractors.

The question of whether an individual is an independent contractor or an employee is one of fact to be determined upon consideration of the facts and the application of the law and regulations in a particular case. Individuals are employees for Federal employment tax purposes if they have the status of employees under the usual common law rules applicable in determining the relationship. Guidance for making the determination is found in three substantially similar sections of the IRS Employment Tax Regulations: 26 CFR 31.3121(d)-1; § 31.3306(i)-1; and § 31.3401(c)-1, which relate to the Federal Insurance Contributions Act, the Federal Unemployment Tax Act, and Federal Income Tax withholding respectively, as well as IRS Revenue Ruling 87-41, 1987-1 C.B. 296. Generally, the relationship of employer and employee exists when the person for whom the services are performed has the right to control and direct the individual who performs the services not only as to the result to be accomplished but also as to the details and means by which that result is obtained. In this connection, it is not necessary that the firm actually direct or control the manner in which the services are performed; it is sufficient that the right to do so be present.

Other factors characteristic of employment are the right of the employer to discharge and the furnishing of tools or a work place. An individual who is not by statute an employee and is not an employee under the common law rules is an independent contractor. Independent contractors are subject to another's control and direction only with respect to the result to be accomplished and not the means and methods to be used.

Consideration must also be given to such factors as the continuity of the relationship and whether the individual's services are an integral part of the business of the employer as distinguished from an independent trade or business of the individual in which the individual assumes the risk of realizing a profit or suffering a loss.

The pertinent facts submitted for my consideration indicate:

1. The ARS nutritional research studies are conducted in accord with the Common Rule for the Protection of Human Subjects (45 CFR Part 46, 7 CFR Part 1c, and ARS Directive 605.1), and in accord with the Nuremburg Code and the Declaration of Helsinki. These require that human subjects' participation in research must be voluntary and uncoerced. Since ARS nutritional research studies follow the above regulations and international agreements, it suggests that the human subjects are volunteers, not employees, who are subject to control and direction. Further, I agree with the ARS that the stipend paid to the human subjects for each day they participate in the research (\$35 per day) is an amount so small that it does not have an undue influence on the decision of the individual to participate in the research.

2. Human subjects who voluntarily participate in the ARS nutritional research studies enter into a consent agreement under which they agree to follow research protocols established by the ARS during the duration of the research study. A continuing relationship between the ARS and the human subjects is not established.

3. The human subjects do not produce a product or provide a service to the ARS during these research studies. Providing samples of blood and normal bodily functions is not an activity pursued as a livelihood by the human subjects.

4. The human subjects control the means and methods used to accomplish the task, i.e., the provision of samples of bodily functions. While the ARS controls the research protocols to be followed, including the schedule of sample collection, the human subjects control their own bodily functions.

5. The ARS provides no tools, supplies, or equipment to the human subjects. The ARS does use instruments during the nutritional research to collect and analyze bodily samples provided by the human subjects, however these instruments are not used by the human subjects.

6. Human subjects are not entitled to sick leave or annual leave and are not covered under any Federal Employee Retirement System.

The reasons stated above indicate that an employment relationship does not exist and support the conclusion stated in the first paragraph of this ruling that, for UCFE program purposes, human subjects who participate in nutritional research studies conducted by the USDA, ARS, do not perform "Federal Service" within the meaning of 5 U.S.C. 8501(1).

This coverage ruling is issued pursuant to redelegation of authority from the Assistant Secretary, in Employment and Training Order No. 2-92, dated April 10, 1992, (published at 57 Fed. Reg. 13760), which is authorized by Section 6 of Secretary's order No. 4-75 (40 Fed. Reg. 18515) (as amended by Secretary's Order No. 14-75).

MARY ANN WYRSCH
Director
Unemployment Insurance Service

DATE

TEUPDI:HCOSTA:paa:11/12/96:S:\UI\DPDI\FEDERAL\UCFE\COVRULIN.971
ROOM S-4518:FPB:219-5616:EXT. 152

cc: WYRSCH (2), CASTILLO, GILLHAM, BALDWIN, COSTA, CHRON